IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Vaquero
Application No.	:	10/813,863
Filed	:	March 31, 2004
Title	:	IOL Injector
Group/Art Unit	:	3731
Examiner	:	Amy T. Lang
Docket No.	:	P03166
Conf. No.	:	5586

APPEAL BRIEF

(Revised in view of Notice of Compliance mailed 9/1/2009)

Mail Stop Appeal Brief --- Patents
P.O. Box 1450
Commissioner for Patents
Washington D.C. 22313-1450

Sir:

By Notice of Appeal filed on May 1, 2009, Applicant appeals the Final Rejection in the above-identified application, and submits this Brief in support thereof. Authorization to charge the fee under 37 CFR 1.17(c) to Deposit Account No. 02-1425 is provided in the transmittal letter accompanying this Appeal Brief.

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I. Real Party in Interest

The real party in interest in this appeal is Bausch & Lomb Incorporated, as evidenced by the Assignment recorded at Reel 014808, Frame 0219.

II. Related Appeals and Interferences

Applicant is not aware of any other appeals or interferences which will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 1, 3-4, 6-13 and 22-25 are pending for examination, with claims 1 and 23 being independent.

Claims 26-28 are withdrawn.

Claims 2, 5 and 14-21 were cancelled.

Claims 1, 3-4, 6-13 and 22-25 were finally rejected in an Office Action dated February 12, 2009. The rejections of claims 1, 3-4, 6-13 and 22-25 are appealed. A copy of the claims, as pending is attached as an Appendix.

IV. Status of Amendments

No amendments have been filed following the Final Rejection of February 12, 2008.

V. Summary of Claimed Subject Matter

Independent claim 1 recites a device for injecting a foldable IOL into an eye (FIG. 1, r.n. 10). The device comprises an injector body (paragraph [0022], line 2; FIG. 1, r.n. 12). The injector body includes a lumen sized to permit the IOL to be transported therethrough (paragraph [0022], lines 3-4; FIG. 1, r.n. 14), the lumen having a proximal end, and an open tip wherethrough the IOL is expressed from said device (paragraph [0022], lines 3-4; FIG. 1, r.n. 16 and 18); and an opening in said injector body, said opening being sized and shaped to receive the IOL and said opening configured and arranged to permit placement of the IOL in a loading bay (paragraph [0023], lines 1-3; FIG. 1, r.n. 26), an inner diameter of the lumen at a location immediately adjacent and distal to the loading bay being less than an inner diameter of the lumen at the open tip (paragraph [0032], lines 3-5); FIG. 2B, r.n. d_1, and d_2).

Claim 23 recites a device for injecting a foldable IOL into an eye (FIG. 1, r.n. 10). The device comprises an injector body (paragraph [0022], line 2; FIG. 1, r.n. 12). The injector body includes a lumen sized to permit the IOL to be transported therethrough (paragraph [0022], lines 3-4; FIG. 1, r.n. 14), the lumen having a proximal end, and an open tip wherethrough the IOL is expressed from said device (paragraph [0022], lines 3-4; FIG. 1, r.n. 16 and 18); and an opening in said injector body, said opening being sized and shaped to receive the IOL into a loading bay of the lumen (paragraph [0023], lines 1-3; FIG. 1, r.n. 26). The device further comprises a moveable compressor connected to the injector body proximate said opening and configured and arranged to compress the IOL when the IOL is disposed in the loading bay (paragraph [0032], lines 13-14 and FIG. 1, r.n. 60 and 26). The lumen has a first diameter at a first location immediately adjacent and distal to the distal end of the loading bay and having a second diameter at the open tip that is larger than the first diameter (paragraph [0032], lines 3-5); FIG. 2B, r.n. d_1, and d_2).

VI. Grounds of Rejection to be Reviewed on Appeal

The grounds of rejection raised by this appeal are:

1. Whether claims 1, 3-4, 6-13 and 22-25 were properly rejected under 35 U.S.C. 103(a) as obvious over Clark in view of Smith.

VII. Argument

1. Claims 1, 3-4, 6-13 and 22-25 were properly rejected under 35 U.S.C. 103(a) as obvious over Clark in view of Smith

A. Discussion of the Cited Prior Art

Clark discloses an instrument for inserting a flexible intraocular lens into an eye (Abstract). The instrument includes a compressor for laterally compressing the lens into a small cross-sectional configuration to pass through an incision (Abstract). The compressor includes retainers along the interior to maintain the side edges of the lens in a substantially planar orientation during compression (Abstract).

An advantage of the inserter of Clark is that, since the side edges of the lens are not folded over onto themselves during compression, the lens doesn't swing open within the eye in order to regain the original shape to prevent injury to the eye during release of the lens from the inserter (col. 2, lines 33-38).

To control the side edges of the lens, each side wall 60, 62 is provided with a retainer which receives and holds the opposite side edges 18a, 18b of an optic 14 to prevent side edges from being folded over or turning when the compressor 40 is moved to its closed position in a compressing station 26 (FIG. 4 and 6A-6D). Clark indicates that the retainers are formed as troughs 68 and 70 (col. 4, lines 54-55). The side edges 18a, 18b of the lens are oriented generally along a central plane (col. 4, lines 41-46). After compression, the sidewalls are spaced apart form a passage through which lens is advanced by a plunger into an eye (col. 4, lines 64-67).

To control the side edges during advancement with the plunger, the lumen of the inserter cannula is provided with sidewalls 109 and troughs 111 to match sidewalls 60, 62 of the compressing station 26 (col. 6, lines 4-7). Clark states that the troughs 111 are aligned with troughs 68, 70 when the compressor is closed to form continuous retention of optic edges 18a, 18b as the lens is advance into the eye (col. 6, lines 7-11).

The free end 119 of cannula 28 is provided with a pair of opposed longitudinal slits 121 in troughs 111 (FIGs. 1-3, 5 and 7) (col. 6, lines 31-33). The slits are wide enough to permit sides 189a, 18b of optic 14 to extend outward beyond the sides of the cannula 28. The slits there

permit lateral expansion of the lens prior to its release into the eye to dissipate the release of force in the unfolding lens (col. 6, lines 31-38).

Smith discloses an insertion tool for intraocular lenses including a rigid tube with a paddle on its distal end (Abstract). The rigid tube and paddle are capable of reciprocating in the rigid tube (col. 1, lines 63-65). The paddle is made of a flexible film and is adapted to fold to a generally closed position as it is retracted into the rigid tube to thereby hold and at least partially surround the intraocular lens (col. 1, line 69 to col. 2, line 4). The lens is placed on the paddle with forceps with a haptic in notch 86 and the paddle is retracted to bring the lens into the distal portion of the tube (col. 3, lines 22-24 and col. 5, lines 22-25). As the lens is retracted into the tube, paddle 22 will fold around the periphery of the lens 21 and the paddle maintains the lens frictionally in place after the paddle is retracted into the tube (col. 5, lines 47-56). Subsequently, the instrument is placed into an incision in the eye and the user operates the inserter to move the paddle distally out of the tube into the eye to deliver the lens into the eye (col. 6, lines 1 and 8-14).

B. The Combination of Clark and Smith is Improper

The combination of Clark and Smith is improper for several reasons, namely the Examiner's stated motivation is improper, and the combination would render the inserter of Clark in operative. Firstly, it is noted that the inserters of Clark and Smith provide very different techniques for folding a lens (Clark using a proximally located compressor and Smith using a paddle that retracts the lens from the distal end of the inserter tube); and each provides a complete solution on its own.

As stated above, the Examiner's rationale for the combination of Clark and Smith is that it would be obvious to one of ordinary skill in the art to include a holder (i.e., a paddle) as taught by Smith to hold the entire laterally-expanded IOL to allow the sides of the optic to be secured with the device prior to delivery. However, in none of the art of record is it stated that it would be desirable to allow the sides of the optic to be secured with the device prior to delivery nor has provided any support for the self-serving allegation that securing of the sides would be desirable. In fact, contrary to the Examiner's allegation, Clark provides a technique that requires

the edges to be exposed to engage the troughs that control the lens edges and therefore mandates that sides of the optic not be secured by something such as the paddle of Clark.

Furthermore, it is required that there is a reasonable expectation of success that the combination work for its stated purpose. It cannot be said that such success is likely, and in fact is impossible, when the paddle Smith surrounds the lens. Accordingly, the troughs 68, 70 and 111 of Clark are rendered incapable of interacting with the edges of the optic to maintain planarity of the edges of the optic, and contrary to the teachings of Clark, continuous retention of optic edges 18a, 18b as the lens is advance into the eye is impossible. It must be said that Clark teaches away from surrounding the lens with a paddle as taught by Smith.

Finally, if attachment of the lens to the paddle is to occur after compression, it is unclear how a lens compressed in the loading bay of Clark could be attached to a paddle as discloses in Smith. The paddle requires the lens haptic to be attached to the paddle (see FIG. 5 and col. 5, lines 22-25 of Smith). However, the lens and paddle (which presumably would be attached to the plunger of Clark) are not even accessible after the compressor of Clark is closed.

Accordingly, the combination of Clark and Smith is improper and withdrawal of the rejections of claims 1, 3-4, 6-13 and 22-25 based on said combination is respectfully requested.

C. Even if Clark and Smith were combined in the manner suggested by the Examiner claims 1, 3-4, 6-13 and 22-25 are patentable over the combination.

Even if the combination of Clark and Smith were proper, which it is not, claims 1, 3-4, 6-13 and 22-25 are patentable over the combination.

The Examiner alleges in the Office Action (on page 3, line 3 from the bottom) that, after the combination of Clark and Smith, it is the paddle that is that forms the lumen that is larger than the rest of the lumen. A "lumen" is defined to be a bore of a tube (Merriam-Webster online dictionary). The paddle (shown in FIGs. 1 and 3 of Smith) when expanded to be bigger than the tube 14 of Smith does not form a bore.

Claims 1 and 23 recite "an inner diameter of the lumen at a location immediately adjacent and distal to the loading bay being less than an inner diameter of the lumen at the open tip." Accordingly claims 1 and 23 are patentable over the proposed combination of Clark and Smith.

Additionally, on lines 1-4 of page 3, the Examiner misconstrued the term "immediately adjacent." The Examiner states that the term "adjacent" means close or near, so the Examiner concludes that the term "immediately adjacent" means immediately close or near. The Applicants submit that such a definition eviscerates the commonly understood meaning of the term "immediately adjacent." Based on the Examiner's definition, the Examiner concludes that the proximal taper of Clark is immediately adjacent.

The Applicants submit that the term "immediately adjacent" means abutting, and that the claim recites "a diameter ... immediately adjacent." Accordingly, the relevant diameter is the abutting diameter, not a diameter that has a substantial segment of the lumen (i.e., the taper) intervening.

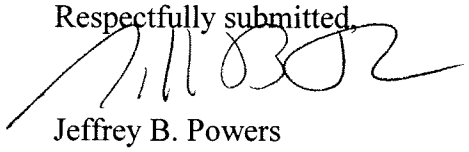
The Applicants submit that the widest diameter of the taper of Clark is all that is immediately adjacent the loading bay. Accordingly, contrary to claims 1 and 23, in an inserter that would result from the Examiner's proposed combination of Clark and Smith, the inner diameter of the lumen at a location immediately adjacent and distal to the loading bay would not be less than an inner diameter of the lumen at the open tip. Accordingly, claims 1 and 23 are patentable over the proposed combination of Clark and Smith.

Claims 3-4, 6-13 and 22, 24-25 depend from a corresponding one of claims 1 and 23 and are patentable over the combination of Clark and Smith for at least the same reasons as claims 1 and 23.

Withdrawal of the rejections of claims 1 and 23 is respectfully requested.

In light of the foregoing arguments, applicants request that the outstanding rejections be reversed and that the pending claims 1-8, 10-14 and 17 be allowed.

Respectfully submitted,



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VIII. Claims Appendix

The claims under appeal are as follows:

1. A device for injecting a foldable IOL into an eye, said device comprising:

an injector body including

(a) a lumen sized to permit the IOL to be transported therethrough, the lumen having a proximal end, and an open tip wherethrough the IOL is expressed from said device, and

(b) an opening in said injector body, said opening being sized and shaped to receive the IOL and said opening configured and arranged to permit placement of the IOL in a loading bay, an inner diameter of the lumen at a location immediately adjacent and distal to the loading bay being less than an inner diameter of the lumen at the open tip.

2. (canceled)

3. The device of claim 1, further comprising a compressor drawer having a leading edge, said compressor drawer attached to said device adjacent said opening and movable to a closed position whereupon said leading edge engages and compresses said IOL when the IOL is in the loading bay.

4. The device of claim 3, further comprising a plunger having a longitudinal shaft and a plunger tip configured to slide within said lumen, said plunger tip configured for engaging and pushing said IOL through said lumen and out said open tip.

5. (cancelled)

6. The device of claim 1 wherein said injector body has an outer diameter which is substantially constant from a point adjacent said IOL when initially placed in said device to said open tip.

7. The device of claim 1 wherein said injector body has an outer diameter which increases along with the increase in diameter of said lumen.

8. The device of claim 1 wherein said lumen comprises a region of increasing diameter, and wherein said region increases gradually in diameter.

9. The device of claim 1 wherein said lumen comprises a region of increasing diameter, and wherein said region includes a step in diameter.

10. The device of claim 6 wherein said lumen comprises a region of increasing diameter, and wherein said region increases gradually in diameter.

11. The device of claim 6 wherein said lumen comprises a region of increasing diameter, and wherein said region includes a step in diameter.

12. The device of claim 7 wherein said lumen comprises a region of increasing diameter, and wherein said region increases gradually in diameter.

13. The device of claim 7 wherein said lumen comprises a region of increasing diameter, and wherein said region includes a step in diameter.

14-21. (cancelled)

22. The device of claim 3, wherein the compressor drawer is slidable relative to the injector body and adapted such that the leading edge translates to engage and compress said IOL.

23. A device for injecting a foldable IOL into an eye, said device comprising:

I.) an injector body including

(a) a lumen sized to permit the IOL to be transported therethrough, the lumen having a proximal end, and an open tip wherethrough the IOL is expressed from said device, and

(b) an opening in said injector body, said opening being sized and shaped to receive the IOL into a loading bay of the lumen,

II.) a moveable compressor connected to the injector body proximate said opening and configured and arranged to compress the IOL when the IOL is disposed in the loading bay,

said lumen having a first diameter at a first location immediately adjacent and distal to the distal end of the loading bay and having a second diameter at the open tip that is larger than the first diameter.

24. The device of claim 23, further comprising a plunger adapted to telescope through the lumen and move the IOL from the loading bay through the open tip.

25. The device of claim 23, wherein the compressor is a compressor drawer.

26. (withdrawn) A method of preparing an IOL for delivery into an eye, comprising:

locating an IOL into an IOL injector;

compressing the IOL to reduce the IOL's cross section;

after said step of compressing, a first step of advancing the IOL down a lumen of the injector without increasing IOLs cross section;

after said first step of advancing the IOL, a second step of advancing the IOL further down the lumen through a lumen portion configured to permit the IOL to increase in cross section; and

after said second step of advancing the IOL, advancing the IOL through an open end of the lumen.

27. (withdrawn) The method of claim 26, wherein the lumen portion terminates at the open end.

28. (withdrawn) The method of claim 26, wherein the step of compressing comprises sliding a compressor drawer to reduce the IOL's cross section.

IX. Evidence Appendix

(None)

X. Related Proceedings Appendix

(None)